REMARKS

Entry of the foregoing and favorable reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. Section 1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, the specification has been amended to insert letters that were inadvertently omitted during the scanning of the present application. Claims 9 to 24 have been canceled as directed to a non-elected invention. Claims 1 to 8 have been amended to place the claims in proper U.S. format. Applicants submit that no new matter has been added via this amendment.

The specification has been objected since letters are missing from various words due to the scanning process. Applicants have amended the specification, which should render this objection now moot.

Claims 1 to 8 have been rejected under 35 U.S.C. §103 (a) as being unpatentable over Haicheur et al in view of Wang et al. For the following reasons, this rejection is respectfully traversed.

In rendering this rejection, the Examiner deems that it would be obvious to a person skilled in the art to modify the construct of the B subunit of Shiga toxin fused to a tumor peptide with extra residues such as cysteine as taught by

Wang et al. Applicants respectfully disagree with the Examiner for the following reasons.

Haicheur et al. disclose constructs of the non-toxic B subunit of Shiga toxin fused to tumor peptides and demonstrate that these constructs can induce specific CTL in mice without the use of an adjuvant. This reference discloses that the particular constructs are capable of binding the Gb3 receptor and target the exogenous antigen to the MHC class I pathway via phagocytosis.

Haicheur et al fail to disclose that the constructs can be used as universal carriers by the addition of a cysteine residue at the C or N terminal end of the B subunit of Shiga toxin. Rather only fusion proteins are taught and there is absolutely no suggestion to modify the constructs of Haicheur et al.

The secondary reference of Wang et al disclose the use of "Structured Synthetic Antigen Libraries" (SSAL), which are composed of peptides synthesized simultaneously, as well as to their use in diagnostic methods, kits, vaccine compositions and pharmaceutical compositions. In this document, there is only a brief, single disclosure showing that cysteine residues can be added to synthetic peptides in order to facilitate the directed coupling of the peptides to a "carrier." Indeed, the specification of Wang et al contains 63 pages of description and the Examiner has focused only on a single sentence of this reference in rendering this rejection and has ignored the rest of the teachings as a whole. Applicants respectfully submit that picking and choosing only those parts of a reference to render this rejection is contrary to the law.

Moreover, even though Wang et al disclose the use of cysteine residues attached to a carrier, those carriers described therein are Bovine Serum Albumin (BSA), Human Serum Albumin (HSA), red blood cells or latex particles. It is well known to those skilled in the art that these carriers pertain to a class of molecules which are used to improve the immunogenic response of the peptides contained in the SSAL. Thus, the universal carrier of the present invention differs from those described in Wang et al. by the process implemented to obtain the immunization. Indeed, immunization is achieved in the present invention by the specific delivery of the antigen into the MHC class I and class II intracellular pathway, instead of being induced by the presence of multiple epitopes on the carrier molecule, as disclosed in Wang et al. Furthermore, the carriers in Wang et al are not used for targeting molecules to Gb3 receptor expressing cells.

Applicants therefore submit that the combination of Haicheur et al and Wang et al fails to render the present invention obvious sine there would be no expectation of success that by adding an additional cysteine unit to the N- or C-terminal of the B subunit of Shiga toxin as well as a molecule linked thereto that this construct could indeed target the Gb3 receptor expressing cells and be internalized, processed and/or expressed in said cell.

Indeed, as described in the present specification, the Shiga toxin B-subunit carries an internal disulfide bond, that participates in maintaining the correct structural conformation of the protein, such that it can bind specifically to the Gb3 receptor and/or trigger the internalization of the construct and thus enter the MHC I and II pathways.

Applicants therefore consider that the skilled artisan would not have altered the constructs of Haicheur et al by the addition of a cysteine residue, as described in Wang at el either at N-ter or C-ter ends of the protein since the addition of a cysteine residue may result in the formation of new internal disulfide bonds, which can disrupt the final structure of the construct as well as the constructs functional properties.

This modification of the B subunit of Shiga toxin would be even more avoided by the skilled artisan since the size of the universal carrier of the present invention is about 90 amino acids, which is extremely small. The prior art of Wang et al describe common carriers such as BSA, which has about 600 amino acids and is not targeted to a receptor thus conformational change is feasible without disrupting the functional properties of the antigens.

In conclusion, Applicants submit that the skilled artisan would not have any expectation of success in modifying the B subunit of Shiga toxin in view of the cited prior art of Haicheur et al in view of Wang et al to achieve a universal carrier having the same functional properties of targeting and delivery.

Thus, in view of the above, withdrawal of this rejection is respectfully requested.

From the foregoing, favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

If the Examiner has any questions concerning this application, the Examiner is requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By _____

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